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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,965	12/02/1997	GEORGE H. LOWELL	359292000110	9909

26694 7590 05/21/2002

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EXAMINER

BUDENS, ROBERT D

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/21/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

08/18/96



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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-27-02☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☐ Claim(s) 1-4, 6-11 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 6-11 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

BEST AVAILABLE COPY

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's request for a Continuing Prosecution Application is acknowledged. Accordingly, FINALITY of the last Office Action is withdrawn.

10 The Examiner acknowledges Applicant's Request for a Continuing Prosecution Application, Paper No. 24, filed February 27, 2002, requesting entry of the Amendment After Final Rejection, Paper No. 21, filed September 27, 2001. In view of Applicant's Request, the status of the claims is as follows: Claim 5 has been canceled; Claims 1-4, 6-9 and newly added claims 10-11 (claims 9-10 in Paper
15 No. 21 renumbered in accordance with 37 CFR § 1.126) are currently pending before the Examiner.

The Examiner acknowledges Applicant's submission of a new Oath and Declaration, attachment to Paper No. 24, filed February 27, 2002. The newly submitted Oath and Declaration is acceptable.

20 Claims 7 and newly added claims 10-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is vague and indefinite in the recitation "ratio range is 1:1" since there is no
25 range in claim 7. Amendment of claim 7 to delete "range" would obviate this rejection. Claim 10 is vague and indefinite in the recitation "mixing gp 160 and proteosomes, combining gp 160 and proteosomes" since it is unclear whether these are two distinct steps in one method or two different methods encompassed within the

same claim. Amendment of claim 10 to more clearly point out and define what is encompassed by the language "mixing" and "combining" would obviate this rejection.

5 Upon review of Applicant's parent application, 07/065,440, Applicant **IS NOT** accorded benefit of the filing date of the earlier filed application. The specification of application Serial No. 07/065,440 does not provide support for gp160-proteosome complexes as presently claimed.

10 Claims 1-4, 6-9 and newly added claims 10-11 remain rejected under 35 U.S.C. § 103 as being unpatentable over Lowell et al. (U) or Lowell et al. (V) or Smith et al. (W) or Avraham et al. (X) in view of Ratner et al. (Y) for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection.
15 Applicant arguments refer to the exemplified recombinant "R32ft" and the presence of specific adjuvants such as alum and discusses the trimeric complexes of gp 160. However, Applicant's arguments are directed to limitations not found in the claimed invention. Applicant's claims are quite broad with respect to the ratios of
20 proteins and proteosomes, to the type of adjuvant and to the desired effect of inducing antibody formation. As stated in the previous rejections, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce proteosome-gp 160 complexes and use them for
25 inducing antibodies for the reasons of record. Even newly added claims 10-11 only add further limitations that the complexes are lyophilized or dialyzed, both very well known techniques in protein purification and storage. Should Applicant desire to rely on the limitations set forth in Applicant's Response, Applicant should
30 amend the claims to reflect those limitations. In the absence of convincing objective evidence to the contrary, the rejection is deemed proper and is maintained.

Serial No. 08/982,965
Art Unit 1648

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
May 20, 2002